Loma Linda Children's Medical Center: NICU

Unit Number: 909-558-4403

Unit Fax Number: 909-558-4241

Therapeutic Hypothermia Pre-Transport Cooling Protocol

Instructions: Use this packet to evaluate patients for **Therapeutic Hypothermia.**

1) Page 2: Criteria and evaluation
2) Page 3: Pre-Transport Cooling Protocol (Fax to referring hospital)
3) Page 4: Consent forms for Cooling (Fax to referring hospital)

Referring Hospital: _____

Referring Doctor: _____

Phone Number: _____

Fax Number: _____

Criteria for Pre-Transport Cooling Protocol

Inclusion Criteria

1) History of an acute perinatal hypoxic event
    a. Abruptio Placentas
    b. Cord Prolapse
    c. Severe fetal heart rate abnormalities such as variable or late deceleration
2) APGAR score ≤ 5 at 5 minutes
3) pH ≤ 7.0 from cord blood or postnatal blood gas at ≤ 1hour of life
4) Base deficit ≥ 16 mEq/L on cord blood or postnatal blood gas at ≤ 1hour of life
5) Need for Ventilation initiated at birth for at least 10 minutes

Exclusion Criteria

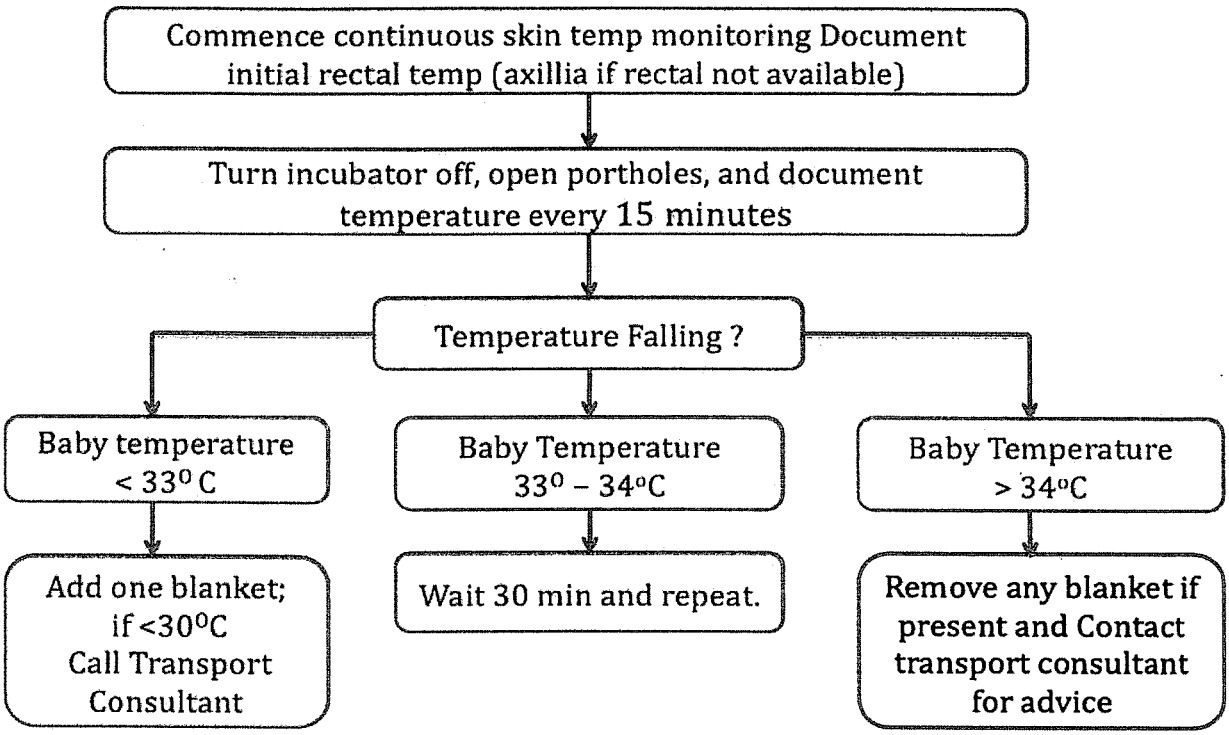
1) If ≥ 6 hrs of life
2) ≤ 36 weeks post menstrual age
3) Absences of hypoxic ischemic encephalopathy or depression
4) Known chromosomal abnormality
5) Presence of major congenital anomalies
6) Severe IUGR ≤ 1800g
7) Infant in extremis no additional care to offer (Talk w/ Attending)

Loma Linda Children's Medical Center: NICU Unit Number: 909-558-4403 Fax Number: 909-558-4241	**Hypoxic Ischemic Encephalopathy Pre-Transport Cooling Protocol** Contact: _____

PRE HOSPITAL COOLING INSTRUCTIONS FOR BABIES WITH H.I.E

Thank you for contacting Loma Linda to evaluate your neonate for therapeutic cooling. Due to the time sensitivity of initiating cooling, we are asking for your assistance in beginning the process. To maximize the benefits of cooling, please start the passive cooling process now. Follow the below diagram and have the nurse caring for the child record the appropriate information. Please **no ice bags or fans to cool.**

Time Passive Cooling Initiated: _____



Target Temperature: 33.5° C

Time	Temp (°C)	HR	BP	RR	Seizures (Y/N)

1Giles S Kendall, et al.*Arch Dis Child Fetal Neonatal* . 2010.187211

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TOTAL BODY COOLING INFORMED CONSENT

Need for total body cooling:

Dr. _____ has informed me about my baby's condition and has explained that based on my infants condition after birth my infant is believed to have a condition known as hypoxic-ischemic encephalopathy (HIE) or severe depression (birth asphyxia) at birth. In addition to affecting the brain, this condition also affects the heart, lungs, kidneys and may lead to death.

Based on studies in the medical literature and information available from national organizations, total body cooling is believed to be beneficial to many infants having this condition. This cooling is designed to lower the metabolic rate of the brain and other tissues and reduce brain damage. Although it has proven beneficial for some infants with HIE, it does not provide benefit for all infants.

Purpose of total body cooling:

I have been informed that my baby will receive standard treatments including ventilatory support with a breathing machine, intravenous medications and nutrition, my infant is at high risk for seizures (convulsions). Infants are given medications to treat evidence of any seizures that are observed. Total body cooling is performed by placing my baby on a cooling blanket that lowers body temperature to approximately 34 degrees Celsius or 94 degrees Fahrenheit for 72 hours. This lowers the metabolic rate (rate of energy use by the organs in the body). When performed early after birth (not greater than 6 hours), results have shown that fewer infants die or have severe handicaps after cooling is performed with customary treatment as compared to infants receiving customary treatment alone. Some hospitals may offer a form of hypothermia for infants older than 6 hours after birth.

Procedures involved with total body cooling:

Procedures directly involved with total body cooling include but are not limited to:

a. Placing infant on a cooling blanket that regulates the "core temperature" measured by a temperature monitoring device placed in the esophagus (food tube) or rectum
b. Lowering infant's temperature to approximately 34 degrees Celsius or 94 degrees Fahrenheit for up to 72 hours and then slowly warming infant by ½ degree every 30 minutes after the initial period of cooling
c. Monitoring and management of the cooling blanket and use of a breathing machine, intravenous fluids and medications as needed
d. Performance of a brain-wave test called an EEG during the period of cooling
e. Performance of imaging studies such as ultrasound scans of the brain and surrounding tissues

During infant's time of cooling, other procedures that are likely to be necessary include:

a. Management of the breathing machine and breathing tube in the upper airway
b. Placement of catheters into blood vessels for monitoring purposes
c. Tests necessary for management of your condition (including tests for blood and urine, radiological tests including x-rays, ultrasounds, CT, MRI/MRS scans and EEGs)
d. Administration of medications (for seizures, sedation, pain, heart and blood pressure support), fluids, blood or blood products
e. Transportation within the hospital
f. Consultation with pediatric neurologist and other subspecialist

It is also possible that other procedures and/or treatments not described above could be required. The risks, benefits, and alternatives of other procedures and treatments will be discussed with me.

Risks of total body cooling and related procedures:

Failure of total body cooling: Placing an infant on a cooling blanket may not improve the infant's condition, may lower the heart rate, be associated with irregularities in the heart rate and cause a drop in the infant's platelet count. Some infants placed on total body cooling die, just as infants who are not cooled.

a. I understand that if in the judgment of the infant's physicians it is found that total body cooling is not helping (or could be harming) my child, then a conference will be held with me to determine whether total body cooling should be stopped.
b. Also, if at any time I decide to withdraw my consent for this procedure, I may inform the neonatologists responsible for the infant's care and a conference will be held with me to consider stopping total body cooling.

Brain Damage: Infants with encephalopathy are susceptible to brain damage. Results from a large national study found that total body cooling was associated with a 19% lower rate of death or disability, a 13% reduction in mental retardation and a 9% reduction in disabling cerebral palsy. Even with these results, permanent and irreversible brain damage (such as mental retardation or cerebral palsy) may still occur.

Other Risks: Risks from prolonged cooling include a slowing of the heart rate, arrhythmias (irregular heart beats) during the re-warming phase and a lowering of the platelet count (cells that assist in helping the blood to clot). The ability for the blood to form a clot may also be altered.
Specific risks to total body cooling include but are not limited to:

a. Over or under cooling from the desired 34-34.5 degrees Celsius/ 94 degrees Fahrenheit.
b. Rewarming the infant faster or slower than desired.
c. During the infant's period of cooling the infant will not be fed orally and will receive nutrition and medications intravenously (into the veins).
d. Equipment failure: The cooling blanket cooling the infant may fail.
e. Unknown risks: There may be new or previously unrecognized hazards or complications associated with total body cooling.

Benefits of total body cooling:

I understand the possible benefit of total body cooling is that the nervous system and brain may recover leading to survival and fewer chances of developing mental retardation or cerebral palsy.

Alternatives to total body cooling:

Should I decide not to consent to the use of total body cooling for my infant, conventional treatment for encephalopathy will continue. I acknowledge that the option of not using total body cooling in favor of other treatments was discussed. I also understand that my refusing to consent to total body cooling does not in any way limit my child's right for any other treatment or for his or her access for further medical care.

TOTAL BODY COOLING INFORMED CONSENT

Acknowledgment:

I understand that while total body cooling is not considered an experimental technique for infants with hypoxic-ischemic encephalopathy, it is a relatively new procedure not yet available in every NICU or hospital. No guarantees have been made to me regarding the effectiveness or safety of this technique, regarding my infant's developmental outcomes or survival. I understand that this treatment must be initiated within 6 hours after birth if my infant has no exclusions to treatment, and that information of the maternal delivery record and infant resuscitation records must be carefully examined by the physicians caring for my infant prior to consideration for total body cooling. Records of my infants participation in the total body cooling program are confidential and may only be disclosed in accordance to applicable state and federal laws.

My decision to consent to total body cooling therapy for my child is made freely as my own choice. It is my understanding that no one requires me to consent to this procedure.
Dr. _____has adequately answered any and all questions I have about my child's condition, the total body cooling procedure and the relative risks and benefits of proceeding or not proceeding with total body cooling. My signature below indicates that I have read, listened to and understood the instructions and information regarding total body cooling.

My infant's physician has explained that by signing this consent form I am acknowledging receipt of information that has helped me understand total body cooling and the re-warming procedure. I also acknowledge that my infant will remain at a higher than normal risk for mental retardation, cerebral palsy and developmental delays and will need to be followed after discharge from the NICU by pediatric neurologists and developmental specialists.

Physician Signature

- ❑ I gave the consentor opportunity to ask questions.
- ❑ I have neither given nor implied any guarantees.
- ❑ I believe that the consentor understands, desires and accepts this procedure.
- ❑ Upon the consentor's request, I have provided them a copy of this document.

Signature/Pager _____
Date_____ Time_____

Interpreter Signature

- ❑ LLUMC Certified Interpreter
- ❑ Qualified Bilingual Staff ❑ Language Line
- ❑ Other (relationship):_____

Interpreter Name (print):_____

Interpreter Signature (if present):_____
Date:_____Time:_____

Language Line Interpreter ID# (if applicable):_____
Date:_____Time:_____

Parent/Legal Representative

- ❑ The risks, side-effects, benefits and alternatives of this procedure have been explained to me and I understand them.

_____
Signature Date Time

_____
Name of Parent/Representative Relationship

Telephone Consent

_____
Person Giving Telephone Consent Relationship

_____
Signature of Witness Date Time